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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,229	09/26/2003	Vinod Sharma	P-11083.00	2880

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EXAMINER

KRAMER, NICOLE R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,229

Applicant(s)

SHARMA, VINOD

Examiner

Nicole R. Kramer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,167,308 ("DeGroot").

DeGroot discloses a method of delivering ATP regimens comprising (a) upon detection of a tachycardia episode, delivering an exploratory ATP sequence of pacing pulses to the heart chamber to elicit a paced depolarization of the heart chamber upon delivery of at least the last delivered ATP pulse (see, for example, col. 2, lines 46-61 in which two series of short series of ATP pulses are delivered); (b) measuring an exploratory return cycle length (RCL) from the last delivered exploratory ATP sequence pacing pulse to the next detected intrinsic depolarization (after delivery of the second series of pulses, the IMD measures the return cycle T4 as described at col. 2, lines 61-63); (c) formulating an ATP regimen having ATP cycle length parameters, wherein the cycle length is formulated as a function of the measured exploratory RCL (depending on a comparison between return cycle T4 and a previously measured return cycle T3, the device either continues delivery of pacing pulses separated by intervals T2 or switches

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to different therapy as described at col. 2, lines 63-66. Since the applied inter-pulse interval varies depending upon whether the measured return cycle T4 increases or does not increase with respect to T3, the ATP cycle length is considered to be "formulated as a function of the measured exploratory RCL"); and (d) delivering the ATP regimen to the heart chamber.

With respect to claim 19, Examiner notes that applicant has invoked 112, 6th paragraph for various claim elements. Examiner considers the means disclosed in DeGroot (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regimens) to be equivalent to the means disclosed in the specification of the current application (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regimens).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-18 and 20-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,167,308 ("DeGroot") in view of U.S. Patent No. 6,400,986 ("Sun et al.").

As described above, DeGroot teaches formulating an ATP regimen having ATP parameters defined as a function of a measured exploratory RCL (depending on a comparison between return cycle T4 and a previously measured return cycle T3, the device either continues delivery of pacing pulses separated by intervals T2 or switches to different therapy as described at col. 2, lines 63-66). In the method disclosed in DeGroot, if the return cycle T4 increases in comparison to return cycle T3, the IMD continues to deliver pacing pulses at the same pacing interval because the increasing return cycle is an indicator that the current pacing interval will successfully terminate the tachycardia. However, if the return cycle T4 does not increase in comparison to return cycle T3, the IMD schedules the next available therapy, which may be a new pacing regimen or a cardioversion pulse (see, for example, col. 5, line 43 - col. 6, line 30). DeGroot fails to teach that the next available therapy may be selected based upon previously successful ATP regimens that successfully terminated a tachycardia when similar return cycles were calculated. Sun et al. teaches an IMD with ATP capability that is programmed to deliver ATP therapy upon detection of a tachycardia by employing a pacing regimen selected from a library, or database, of previously successful or unsuccessful pacing protocols (see col. 2, lines 20-53). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method and device of DeGroot to select the next available therapy based upon previously successful ATP regimens that successfully terminated a tachycardia as taught by Sun et al. in order to terminate the tachycardia as quickly and efficiently as

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possible by selecting a pacing regimen that successfully terminated a tachycardia when similar return cycles were calculated.

With respect to claims 3, 21, 25, and 36, Sun et al. teaches the use of success/failure counters associated with each pacing protocol contained in the library. After each attempt of ATP therapy using a particular protocol, the relevant counter is incremented to indicate the success or failure of the protocol in terminating the arrhythmia (see, for example, col. 2, lines 54-59).

With respect to claims 4-7, 15-16, 22, 26-29, and 37-38, DeGroot detects whether a tachycardia is occurring (see, for example, step 200 of Fig. 4a) and also detects whether the tachycardia terminates in response to delivered ATP pacing therapy (see col. 5, lines 55-60). Detection of whether the tachycardia has terminated includes determining a post-ATP rate (see col. 5, lines 55-60). Although not explicitly stated, DeGroot utilizes a pre-ATP rate to detect whether a tachycardia episode is occurring (in the alternative, Applicant admits that it is known for a ICD to employ tachycardia classification algorithms that utilize detected heart rates in order to detect a tachycardia; see Applicant's specification at page 2. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the IMD of DeGroot to detect the pre-ATP rate in order to detect a tachycardia as is well known in the art in order to accurately detect a tachycardia condition). If the post-tachycardia rate is still determined to be a tachycardia but is different from the pre-ATP rate (i.e., if the tachycardia rate is decelerating, the same, or accelerating), it would have been obvious to one having ordinary skill at the time of applicant's invention to modify the combined

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IMD of DeGroot and Sun et al. to record in the result table/database whether the unsuccessful pacing regimen resulted in accelerating or non-accelerating tachycardia rate in order to provide a physician with more information regarding the effect of a particular pacing regimen on the patient's tachycardia condition. Further, if the tachycardia condition is deemed to be accelerating, it is known in the art that a cardioversion or defibrillation may be required (see, for example, U.S. Patent No. 4,998,974 to Aker).

With respect to claims 8-10, 18, and 30-32, DeGroot discloses that if the return cycle T4 increases in comparison to return cycle T3, the IMD increases the number of ATP pulses delivered (the IMD continues to deliver pacing pulses at the same pacing interval because the increasing return cycle is an indicator that the current pacing interval will successfully terminate the tachycardia). In addition, DeGroot discloses that if the return cycle T4 does not increase in comparison to return cycle T3, the IMD schedules the next available therapy, which may be a new pacing regimen or a cardioversion pulse (see, for example, col. 5, line 43 - col. 6, line 30). The new pacing regimen may include reducing the inter-pulse pacing interval (see col. 6, lines 20-25).

With respect to claims 11-12, 14, 17, 23, and 34, Sun et al. teaches that the information contained in the success/failure counters may be used to calculate a success/failure ratio (see, for example col. 2, lines 59-63 and col. 6, lines 1-37). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method and device of DeGroot to select a therapy having the

highest stored efficacy as taught by Sun et al. in order to terminate the tachycardia as quickly and efficiently as possible.

With respect to claims 19-38, Examiner notes that applicant has invoked 112, 6th paragraph for various claim elements. Examiner considers the means disclosed in DeGroot and or Sun et al. (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments) to be equivalent to the means disclosed in the specification of the current application (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments).

Response to Arguments

5. With respect to the rejections based on Sharma et al. (U.S. Patent Application Publication 2004/0106956), Applicant's arguments filed 7/20/06 have been fully considered and are persuasive. The amendments to claims 1 and 19 overcome the anticipation rejection based on Sharma et al., and thus the rejection has been withdrawn.

6. With respect to the rejections based on DeGroot, Applicant's arguments/amendments filed 7/20/06 have been fully considered but they are not persuasive. Applicant argues that DeGroot fails to disclose "formulating an ATP regimen having ATP cycle length parameters, wherein the cycle length is formulated as a function of the measured exploratory RCL" because the ATP parameters in Degroot are not a function of the measured exploratory RCL. Applicant argues that the ATP

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parameters (e.g., the inter-pulse interval) are established as a function of the interval T2 rather than the return cycle T4 (see pages 22-23 of arguments filed 7/20/06). As previously stated in the Advisory Action mailed 6/30/06, Examiner respectfully disagrees. In the method disclosed in DeGroot, **the parameters of the delivered ATP regimen depends upon the relationship of return cycles T4 and T3** - that is, 1) the device continues delivery of pacing pulses separated by intervals T2 if the return cycle T4 increases in comparison to return cycle T3 because the increasing return cycle is an indicator that the current pacing interval will successfully terminate the tachycardia, or 2) the device switches to a different pacing regimen preferably having an inter-pulse interval somewhat less than T2 if the return cycle T4 does not increase in comparison to return cycle T3 (see col. 2, line 63 - col. 3, line 3; see also col. 5, line 43 - col. 6, line 30). Since the applied inter-pulse interval varies depending upon whether the measured exploratory RCL (that is, the return cycle T4) increases or does not increase with respect to T3, the ATP cycle length is considered to be "formulated as a function of the measured exploratory RCL."


Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


NRK
8/14/06


George Manuel
Primary Examiner